

SCHEMA – PROTOCOL MTCT

- TITLE:** A phase III trial to determine the efficacy and safety of an extended regimen of an antiviral therapy in infants born to HIV-infected mothers to prevent vertical HIV transmission during breastfeeding.
- DESIGN:** Randomized, double-blind, placebo-controlled trial.
- POPULATION:** HIV infected women and their breastfeeding infants.
- DURATION:** Mothers and infants will be followed for 18 months. Total duration of trial approximately 3.5 years.
- PRIMARY OBJECTIVE(S):** To compare the rate of HIV infection at six months in infants determined to be HIV uninfected at birth in each arm.
- To evaluate the safety and tolerance of the extended ARV regimen in infants.
- SECONDARY OBJECTIVES:** Compare the relative rates of HIV infection in infants over 18 months in the two arms.
- To compare infant survival rates over 18 months in the two arms.
- Determine the frequency, type, and duration of ARV resistant strains of HIV in the maternal plasma and breast and the relationship with MTCT.
- Determine the frequency, type, and duration of ARV resistant HIV strains in the plasma of infants who become HIV-infected.

SCHEDULE OF MATERNAL EVALUATIONS FOR THE FIRST 12 MONTHS - PROTOCOL MTCT

Evaluations	Screening	Labor / Delivery	Post Partum					
			2 wks	6 wks	3 mos	6 mos	12 mos	d/c
	3rd trimester or on or before day 3 pp	(on or before day 3 pp)						
Obtain Informed Consent	X							
Determine HIV Status	X							
Medical history and Physical examination	X	X	X	X	X	X	X	X
Infant feeding options counseling	X	X	X	X	X	X	X	X
CD4+ and CD8+ cell counts	X	X	X	X	X	X	X	X
HIV RNA		X		X	X	X	X	
Hematology	X	X	X	X	X	X	X	X
Chemistry panel	X	X	X	X	X	X	X	X
Specimen storage: serum	X	X	X	X	X	X	X	X
Specimen storage: plasma	X	X	X	X	X	X	X	X
Specimen storage: breast milk			X	X	X	X	X	X

SCHEDULE OF INFANT EVALUATIONS FOR THE FIRST 12 MONTHS - PROTOCOL MTCT

Evaluations	Enrollment/ Randomization (on or before day 3 post birth)	2 wks	4 wks	6 wks	8 wks	3 mos	4 mos	5 mos	6 mos	9 mos	12 mos	d/c
Birth and neonatal medical history	X											
Infant feeding practices assessment		X	X	X	X	X	X	X	X	X	X	X
History and Physical examination	X	X	X	X	X	X	X	X	X	X	X	X
Assessment of adherence to ARV regimen		X	X	X	X	X	X	X	X			
Hematology	X	X		X		X			X		X	X
CD4+ and CD8+ cell counts		X		X		X			X		X	X
Chemistry Panel	X	X		X		X			X			
Roche Amplicor HIV-1 DNA PCR	X	X		X		X			X	X	X	
HIV EIA or Rapid HIV Test												X
Specimen storage: plasma	X	X		X		X			X		X	X